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09/448378 378	11/23/99	BRASEL	K	2836-D
APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.	

022932  
IMMUNEX CORPORATION  
LAW DEPARTMENT  
51 UNIVERSITY STREET  
SEATTLE WA 98101

HM22/1009

GAME EXAMINER

ART UNIT 4	PAPER NUMBER
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1644

10/19/01

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6/28/01☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 6, 7, 10, 22-56 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 6, 7, 10, 22-56 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.
2. The request, filed 6/28/01 (Paper No. 17), for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/448,378 is acceptable and a CPA has been established  
An Office Action on the CPA follows.
3. Applicant's amendment, filed 6/28/01 (Paper No. 17), has been entered.  
Claims 6, 20, 22-39 and 44-56 have been amended.  
  
Claims 1-5, 8-19 and 21 have been canceled previously.  
  
Claims 6, 7, 20 and 22-56 are pending.
4. Applicant is invited to verify that the instant claims have written support and enablement under 35 USC 112, first paragraph, for the instant claims to USSN 08/539,142, filed 10/4/95.
5. Applicant should amend the first line of the specification to update the status of the priority documents.
6. Applicant is reminded that affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.  
  
Also, applicant is reminded that the Petition to Correct Inventorship under 37 CFR § 1.48(a), filed 6/28/01, is not signed by Charles Malizewski. Also, there does not appear the appropriate statement by the assignee and new oath and declaration that should accompany this petition in this application.
7. To avoid new matter rejections under 35 U.S.C. § 112, first paragraph, applicant should point out the written description of the limitations with respect to the sequences set forth in claims 25-30 and 34-39.
8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.
9. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected  
  
Applicant is required to identify the nucleotide and amino acid sequences in the specification with SEQ. ID NOS.

The current address of the ATCC is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Trademarks should be capitalized or accompanied by the <sup>TM</sup> or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicant is reminded that the following and should amend the specification accordingly.

Appropriate corrections are required

10. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 6, 7, 20 and 22-53, drawn to methods of augmenting immune responses by administering flt3-ligand, classified in Class 424, subclass 85.1.

II. Claims 54--56, drawn to methods of treating cancer by administering flt3-ligand and dendritic cells, classified in Class 424, subclasses 85.1 and 93.71.

Applicant is invited to clarify whether the administration of flt3-ligand is in vivo or ex vivo, which may be subject to further restriction.

11. Inventions I and II are different methods, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

12. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

13. This application contains claims directed to the following patentably distinct species of the claimed Group I (and Group II, if claimed) : wherein one of the following is also administered.

- A) GM-CSF,
- B) IL-4,
- C) TNF- $\alpha$ ,
- D) IL-3,
- E) c-kit ligand, or
- F) GM-CSF-IL-3 fusions.

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6-7 are generic.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
October 9, , 2001